REMARKS

Formal Matters

Claims 1-30 are pending and Claims 1-30 were examined and rejected.

Claims 1, 7 and 25 have been amended to specify that the first and second structural means are flexible. Support for this amendment may be found in the specification and originally filed Claim 3 which is herein cancelled.

The Abstract has been amended to replace the word "means" with the word "members".

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein and allow Claims 1-2, 4-30, the only claims pending after entry of the amendments set-forth herein. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as acquiescence to any objection or rejection of any claim and without intent to surrender any subject matter encompassed by the originally filed claims (i.e., the pre-amended claims). The applicants expressly reserve the right to pursue any subject matter encompassed by the originally filed claims in one or more continuation and/or divisional applications.

Furthermore, the cancellation of Claim 3 is made without prejudice to renewal, without intent to acquiesce to any rejection, and without intent to surrender any subject matter encompassed by the canceled claims. The applicants expressly reserve the right to pursue any canceled subject matter in one or more continuation and/or divisional applications.

No new matter has been added. Accordingly, the Applicants respectfully request entry of the amendments.

Objection to the Specification

The Abstract of the disclosure is objected to because the term "structural means" is used. The Abstract has been amended to replace the word "means" with the word "members". Accordingly, the Applicants respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §102

Claims 1-26 and 28-30 are rejected under 35 U.S.C. §102(b) as being anticipated by Kaster (US Patent No. 4,366,819).

Under current case law, a reference does not anticipate a claim unless "all of the elements and limitations of the claim are found within [that]...reference...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of invention." Scripps Clinic v. Genentech, Inc., 18 USPQ2d 1671, 1672 (Fed. Cir. 1992).

Therefore, in order for a claim to be anticipated by a reference, each and every limitation must be found in that reference. The Applicant respectfully submits that each and every claimed limitation is not found in the cited reference.

Independent Claims 1, 7, 14, 22 and 25, and the claims that depend therefrom, specify a first structural means having a tubular region that terminates in a lip at one end and a second structural means having a tubular region that terminates in a lip at one end. However, Kaster does not teach first and second structural means, each having the structure claimed in the subject claims.

Kaster teaches an anastomotic fitting that includes a tube 12, ringflange 14 , fixation ring 16 and a locking ring 18. In making this rejection, the Examiner indicates that tube 12 and flange 14 (assertedly the lip) are first structural means having a tubular region that terminates in a lip at one end and rings 16 and 18 (assertedly the lip) are second structural means having a tubular region that terminates in a lip at one end. However, the Applicants respectfully submit that the structure asserted by the Examiner is not taught in Kaster.

For example, tube 12 and ringflange 14 do not constitute a tubular structure that terminates in a lip at one end. Specifically, Kaster teaches that tube 12 has an inflow end 12d and an outflow end 12f. In use of the anastomotic fitting of Kaster, a graft vessel 30 is inserted through tube 12 from the outflow end 12f to the inflow end and everted over the leading edge of tube 12 at the inflow end. It is then that ringflange 14, which is a separate component from tube 12, is positioned over the tube/graft. (see paragraph bridging cols. 10-11) Positioning the ringflange 14 about the tube/graft is accomplished by spreading the ringflange and "[t]he inflow end of the tubed-graft is placed into the expanded central aperture 14b of the ringflange 14." (col. 11, lines 11-13). As shown in Fig. 1 for example, ringflange 14 is positioned over about two thirds of tube 12. Accordingly, tube 12 does not terminate in a lip at one end. Instead, ringflange 14 is a separated component from tube 12 and is positioned about a substantial portion of tube 12 to overlay the tube/graft portion. In other words, tube 12 and ringflange 14 do not identify or otherwise indicate a tubular region that terminates in a lip at one end as tube 12 does not terminate in ringflange 14.

An analogous argument may be made with regard to fixation ring 16 and a locking ring 18 which the Examiner asserts identifies a second structural means having a tubular region that terminates in a lip at one end. More specifically, as shown for example in Fig. 1, fixation ring 16 and locking ring 18 are two separate components. In use, the outflow end of a graft is passed through the central aperture 16b of fixation ring 16 and the fixation ring 16 is advanced from the distal end of the graft to the outflow end 12f of tube 12. (see paragraph bridging cols. 11-12) Kaster teaches that "[t]he locking ring 18 is the last component of the anastomotic fitting 10 to be installed." The free end of the graft is passed through the central aperture of locking ring 18 and the ring is advanced the length of the graft and is positioned on a portion of tube 12 by expanding the locking ring 18. However, the locking ring 18 is only positioned with respect to the fixation ring 16 in an "abutting contact". (paragraph bridging cols. 12-13). In other words, fixation ring 16 and locking ring 18 do not identify or otherwise indicate a tubular region as Kaster teaches that they are both configured as rings having central apertures. However, assuming arguendo that locking ring 18 may be considered a tubular region - as seems to be asserted by the Examiner, locking ring 18 does not terminate in a lip at one end as the abutting contact of fixation ring to the locking ring does not indicate such a structure as these two rings are merely placed adjacent to each other, i.e., in an abutting contact. As such locking ring 18 does not terminate in fixation ring 16, i.e., does not terminate in a lip at one end.

Accordingly, for at least the reasons described above, Kaster does not anticipate Claims 1-26 and 28-30 under 35 U.S.C. §102(b). As such, the applicants respectfully request that this rejection be withdrawn.

Claims 1-13 and 25-28 are rejected under 35 U.S.C. §102(e) as being anticipated by McClellan (US Patent No. 6,007,576).

As amended, Claims 1-2, 4-12 and 25-28 specify that the first and second structural means are flexible. However, McClellan teaches an anastomotic implant that is rigid. More specifically, McClellan teaches an anastomotic apparatus that includes a first element and a second element. In describing these two elements, McClellan makes clear that these two are rigid. For example, the abstract specifically states "An anastomotic apparatus includes a first rigid element and a second rigid element." (emphasis added). Furthermore, McClellan repeatedly teaches that the two elements are rigid and the benefits that the rigidity imparts to the implant.

For example, in summarizing the invention, McClellan teaches: "An engagement of the first element with the second element produces a rigid apparatus structure..." (col. 2, lines 10-12; emphasis added); "The first element is formed of a rigid material or combination of materials." (col. 2, lines 23-24; emphasis added); and "The second element is preferably fabricated from a material which is either rigid or semi-rigid, whereby upon an engagement of the first element and the second element, a construction is formed which is generally rigid..." (col. 2, lines 61-64; emphasis added).

In further describing the implant, McClellan teaches the following:

"The first tubular member 11 and the first flange 12 are secured to one another and are manufactured of materials of sufficient rigidity that the orientation of the longitudinal axis 19 is spatially fixed relative to the longitudinal axis 41." (col. 4, lines 17-21; emphasis added).

"The first element 10 is fabricated to be generally rigid. In preferred constructions the first element 10 may be constructed of materials which exhibit higher moduli of elasticity and rigidity with minimal or no creep. Some materials which are contemplated for use in manufacturing the first element are titanium, stainless steel, graphite, and some non-deformable plastics such as ultrahigh density polyethylene (UHDPE), polycarbonate and acrylonitrile-butadiene-styrene copolymer (ABS). Some ceramic materials may also be used...A rigid apparatus of the instant invention is directed to preserve the inlet and outlet geometries thereby increasing the level of performance and patency of the anastomosis and the graft." (col. 4, lines 44-62).

"In preferred embodiments of the invention the first element 10 is manufactured from a material which provides a surface which is inelastic, firm, rigid, and non-bendable thereby rendering the first element suitable for being coated with a nonthrombogenic material such as with a pyrolytic carbon coating." (sentence bridging cols. 4-5)

"The second flange 22 of the second element 20 includes an upper surface 31 and a lower surface 33. The surfaces 31 and 33 are disposed about a longitudinal axis 67. The second flange 22 and the second tubular portion 21 are fabricated of rigid materials such that the respective longitudinal axes 67 and 63 of these members are retained in a fixed spatial relationship to one another." (col. 5, lines 59-65; emphasis added)

"In preferred constructions, the rigidity of the construction of the two elements 10 and 20 and the nature of their engagement define a structure wherein the two elements are retained fixedly together. This in turn provides the user with a fixed egress angle for the flow of blood out of the blood vessel 16. Due to the rigidity of the construction of the two elements and their engagement the longitudinal axis 19 is retained in a fixed spatial orientation relative to the longitudinal axes 63 and 67. In the most preferred constructions, all of the longitudinal axes 19, 41, 63 and 67 are held in fixed orientations relative to one another upon the engagement of the two elements 10 and 20." (col. 7, lines 11-22; emphasis added).

Accordingly, McClellan clearly teaches a rigid implant made-up of two rigid components. In making this rejection, the Examiner points to the teachings of McClellan at col. 4, lines 44-62. However, as noted above, this passage explicitly teaches a rigid first element. More specifically, this passage is generally directed to the first element and describes that "The first element 10 is fabricated to be generally rigid". Furthermore, in describing materials contemplated for use in the manufacture of the first element, this passage recites rigid materials, e.g., titanium, stainless steel, graphite, non-deformable plastics, ceramics, and the like. This passage also describes the beneficial features imparted to the apparatus due to the rigidity and notes "A rigid apparatus of the instant invention is directed to preserve the inlet and outlet geometries thereby increasing the level of performance and patency of the anastomosis and the graft." Accordingly, the Applicants respectfully submit that this cited passage explicitly teaches a rigid first element and a rigid apparatus.

Accordingly, for at least the reasons described above, McClellan does not anticipate Claims 1-2, 4-12 and 25-28 under 35 U.S.C. §102(e). As such, the applicants respectfully request that this rejection be withdrawn.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-132CIP.

Respectfully submitted,
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